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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,763	10/16/2000	Daniel D. Rocky	245-55928	4232

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/15/2002

*Revised 10/14/02*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/673,763

Applicant(s)

ROCKEY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 5-12 and 19-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-12 and 19-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Applicants' Response to Restriction, received 6 June 2002, paper #7, is acknowledged. Applicants elect, with traverse, Invention VII, claims 5-12, drawn to IncA *C. trachomatis* protein (SEQ ID NO:14) and first method of use (vaccination).

Applicant's traversal is on the grounds that the claims are not directed to 19 independent and distinct inventions as alleged by the Examiner and that in light of the cancellation and amendment of the claims, it is necessary to recombine Groups VI and VII to properly evaluate the pending claims. After consideration of applicants' cancellation and amendment of the claims, claims directed to original Inventions VI and VII, i.e., IncA proteins designated SEQ ID NO:8 and 14 are hereby recombined. However, the requirement for all of the other inventions, i.e., I-V and VIII-XIX is still deemed proper for the original reasons of record and is therefore made FINAL.

2. Claims 1-4 and 13-18 have been canceled. Claims 5-12 have been amended. New claims 19-30 have been added.
3. Claims 5-12 and 19-30 are pending and under consideration.

### Specification

4. The disclosure is objected to because of the following informalities:
  - a) page 9, line 25, "infectio-specific" should be "infection specific",

Appropriate correction is required.

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**Claim Rejections - 35 USC § 112**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5-12 and 19-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5-12 and 19-20 are drawn to a vaccine preparation comprising  $\geq 1$  purified peptide and a method of vaccination.

While the specification teaches the isolation of *inc* genes, production of proteins, and reactivity of plaques comprising said proteins with convalescent antisera, the specification does not contain any examples of actual vaccines, methods of making vaccines, or methods of vaccination, merely prophetic statements of what the proteins may be used for. Therefore, the specification does not reasonably convey that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., a vaccine.

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Claims 21-30 are drawn to an immune response inducing composition comprising  $\geq 1$  purified peptide and a method of immunization.

While the specification teaches the isolation of *inc* genes, production of proteins, and reactivity of plaques comprising said proteins with convalescent antisera, the specification does not contain any examples of actual methods of making an immune response composition or immunization of recipients, merely prophetic statements of what the proteins may be used for. Therefore, the specification does not reasonably convey that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., an immune response inducing composition.

#### **Claim Rejections - 35 USC § 102**

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 21 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al (WO9511309, 27April1995).

The instant claims are drawn to an immune response inducing composition comprising  $\geq 1$  purified peptide comprising  $\geq 5$  contiguous amino acids of SEQ ID NO:14 and a method of immunization of a mammal.

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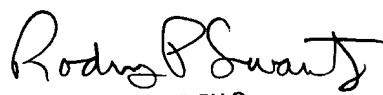
Zhu et al teach the instant inventions by inducing antibody production in mice utilizing a composition of mitosin, which comprises  $\geq 5$  contiguous amino acids of SEQ ID NO:14 (Figure 8B-1; page 31, line 31 to page 32, line 15).

### Conclusion

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

August 14, 2002